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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,338	02/08/2002	Cecilia Anders	P31731X1C1	2718

7590 11/10/2003

GLAXOSMITHKLINE  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939

EXAMINER
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KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/071,338	ANDERS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-37 and 45-49 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Application Status***

1. By virtue of a preliminary amendment filed December 26, 2002, Claims 1-37 and 45-49 are pending in the instant Office action.

### ***Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-3, 5-14 and 25-29, drawn to DNA and related products of the orfup3 gene, classified in class 536, subclass 23.7.
  - II. Claims 1-3, 5-14 and 25-29, drawn to DNA and related products of the orfup2 gene, classified in class 536, subclass 23.7.
  - III. Claims 1-14 and 25-29, drawn to DNA and related products of the orfup1 gene, classified in class 536, subclass 23.7.
  - IV. Claims 1-3, 5-13 and 25-29, drawn to DNA and related products of the cas1 gene, classified in class 536, subclass 23.7.
  - V. Claims 1-3, 5-14 and 25-29, drawn to DNA and related products of the orfdwn1 gene, classified in class 536, subclass 23.7.
  - VI. Claims 1-3, 5-14 and 25-29, drawn to DNA and related products of the orfdwn2 gene, classified in class 536, subclass 23.7.
  - VII. Claims 1-3, 5-14 and 25-29, drawn to DNA and related products of the orfdwn3 gene, classified in class 536, subclass 23.7.
  - VIII. Claims 15-18, 20 and 37, drawn to process for improving 5R clavam production by manipulating the orfup3 gene, classified in class 435, subclass 117.
  - IX. Claims 15-18, 20, and 37, drawn to process for improving 5R clavam production by manipulating the orfup2 gene, classified in class 435, subclass 117.
  - X. Claims 15-20 and 37, drawn to process for improving 5R clavam production by manipulating the orfup1 gene, classified in class 435, subclass 117.
  - XI. Claims 15-17, 20, and 37, drawn to process for improving 5R clavam production by manipulating the cas1 gene, classified in class 435, subclass 117.
  - XII. Claims 15-18, 20, and 37, drawn to process for improving 5R clavam production by manipulating the orfdwn1 gene, classified in class 435, subclass 117.
  - XIII. Claims 15-18, 20, and 37, drawn to process for improving 5R clavam production by manipulating the orfdwn2 gene, classified in class 435, subclass 117.
  - XIV. Claims 15-18, 20, and 37, drawn to process for improving 5R clavam production by manipulating the orfdwn3 gene, classified in class 435, subclass 117.

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- XV. Claims 21-24, drawn to process for screening for microorganisms with high 5R clavam production, classified in class 435, subclass 4.
- XVI. Claims 30-36 and 45-49, drawn to clavulanic acid, classified in class 540, subclass 347.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I-VII are related as genes encoding polypeptides involved in 5S clavam biosynthesis. However, each of these genes is distinct by virtue of their distinct structure and function. These nucleic acids encode polypeptides which each have distinct functional properties catalyzing unique reactions in the biosynthetic pathway of the 5S clavulanic acid. Furthermore, these nucleic acids encode polypeptides having distinct structural properties with varying amino acid sequence, and thus varying nucleic acid sequence, lacking any consensus among the Groups. Thus, members of Groups I-VII are patentably distinct, each from the other. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, for example, restriction for examination purposes as indicated is proper; the searches are wholly distinct using distinct SEQ ID NOs.

Groups VIII-XIV are related as methods of manipulating genes encoding polypeptides involved in 5S clavam biosynthesis. These Groups are distinct, each from the other, for the reasons cited above for the polynucleotides. Because these inventions are distinct for the reasons given above and the search required for Group VIII is not required for Group IX, for example, restriction for examination purposes as indicated is proper; the searches are wholly distinct using distinct SEQ ID NOs.

Each of Groups I-VII are related to Groups VIII-XIV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the DNA can be used for a materially different process of using that product, such as in the production of recombinant polypeptides encoded by the DNA. Thus, Groups I-VII are each patentably distinct from Groups VIII-XIV.

Groups I-VII are related to Group XV as both involving products of high 5R clavam biosynthesis. However, the processes of Group XV neither make nor use the products of Groups I-VII specifically. Thus, Groups I-VII are patentably distinct from Group XV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups I-VII are related to Group XVI because the DNA Groups encode proteins that produce clavulanic acid, the product of Group XVI. However, these Groups are wholly distinct based on the distinct structure and function of the claimed products. Thus, Groups I-VII are patentably distinct from Group XVI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups VIII-XIV are related to Group XV by virtue of involving 5R clavam biosynthesis genes. However, the method steps of Groups VIII-XIV are wholly distinct from Group XV producing wholly distinct products. Thus, Groups VIII-XIV are patentably distinct from Group

XV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups VIII-XIV are related to Group XVI as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, clavulanic acid can be isolated from non-recombinant *S. clavuligerus*. Thus, Groups VIII-XIV are patentably distinct from Group XVI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group XIV is related to Group XV by virtue of the microorganisms identified in Group XIV effectively produce the product of Group XV. However, the methods of Group XIV neither make nor use clavulanic acid itself. Thus, Groups XIV and XV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

#### ***Notice of Possible Rejoinder***

4. The Examiner notes that if product claims in Groups I-VII or Group XVI are found directed to an allowable product, then process claims in Groups VIII-XIV, which are directed to processes of making or using the patentable product, previously withdrawn from consideration as

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a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re Ochiai*, and *In re Brouwer*). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

### ***Election***

5. A telephone call was made to Andrea Lockenour on November 3, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

### ***Conclusion***

6. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



KMK  
November 3, 2003